REMARKS/ARGUMENTS

Applicant has filed this response to the Office Action dated November 9, 2010. Claim 3 is pending for prosecution. Claim 3 is independent and has been amended. Applicant respectfully requests the withdrawal of all outstanding rejections and objections and the allowance of all pending claims.

I. Claim Rejections - 35 U.S.C. § 103

A. Obviousness

When determining the question of obviousness, underlying factual questions are presented which include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art at the time of the invention; (3) objective evidence of nonobviousness; and (4) the differences between the prior art and the claimed subject matter. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Moreover, with regard to the last prong of the *Graham* inquiry, "[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit." KSR International v. Teleflex Inc., 127 U.S. 1727 (2007).

The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). The level of ordinary skill in the art in this area may be determined by looking to the references of record. In re GPAC, Inc., 57 F.3d 1573, 35 USPQ2d 1116 (Fed. Cir. 1995). The references of record in this case reveal that a moderately high level

of sophistication is present in the subject area of the subject area of the instant application. Thus, Applicant submits that, as substantiated by the cited references, those with a bachelor's degree in food technology or the like would most likely be a person with ordinary skill in this field of endeavor.

With respect to objective evidence of non-obviousness, the Applicant submits that the record supports the conclusion that there are long-felt but unsolved needs met by the present invention. As evidenced by the attached Declaration of Dr. Stephanopoulos (the "Declaration"), there is no evidence in the cited prior art of a method to produce ready-to-eat meat products based on entire-muscular tissue, wherein olive oil has been stably incorporated. There was certainly a need in the industry for this technology. There was not a lack of interest in the development of such products, but rather the technological difficulties implicated in the making of these types of products were present. Instability in the incorporation of oil is indeed expected to result in the phenomena stated by the Applicant in paragraphs [0008]-[0009] of App. 10/577,659. The claimed invention has thus addressed a long-felt need in the industry and succeeded to achieve this goal. For at least this reason the Applicant respectfully submits that the claimed invention is not obvious in view of the cited references.

Finally, prima facie obviousness requires that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. This motivation-suggestion-teaching test informs the *Graham* analysis. "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references," there must be "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is

correct." In re Kahn, (Fed. Cir. 2006). The *KSR International* decision by the Supreme Court has not eliminated the motivation-suggestion-teaching test to determine whether prior art references have been properly combined. Rather, in addition to the motivation-suggestion-teaching test, the Court discussed that combinations of known technology that are "expected" may not be patentable. Stated in the affirmative, therefore, combinations are non-obvious and patentable if unexpected. In the present application, no single prior art reference nor any combination thereof (legitimate or otherwise) meets the claimed limitations of Applicant's invention.

II. Rejection of Claim 3

Claim 3 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Domazakis (U.S. Pub. No. 2003/0049364) in view of Hendricks et al. (U.S. Pat. No. 5,053,237) and Brandt (Marinades "Meat" Challenges publication). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Examiner asserts that Domazakis teaches most steps of the method as claimed in claim 3 of the present invention. The Examiner admits that Domazakis does not teach the "entire muscular tissue" in relation to the meat product of the present invention. The Examiner asserts that Hendricks teaches this aspect of the present invention. The Applicant will first show how Domazakis deals with different types of meat products and therefore is inapplicable and then will discuss how Hendricks combined with Domazakis does not disclose each and every limitation of the present application. Generally, the prior art alone nor in combination does not (1) brine the entire muscular tissue, (2) tumble the entire muscular tissue, and then (3) tumble the entire muscular tissue with olive oil in order for the olive oil to be absorbed by the muscular tissue.

On page 4 of the Office Action dated 4/21/2011, the Examiner asserts that "one of

ordinary skill in the art would have been motivated to modify Domazakis and to employ the process of incorporation of olive oil in the 'entire muscular tissue' meat pieces as disclosed by Hendricks [..]. One of ordinary skill in the art would have been motivated to do so, in order to increase consumption of health-beneficial unsaturated fats". The Applicant respectfully disagrees with the Examiner in several aspects. For reasons set forth herein, a person of ordinary skills could not reach the claimed method underlined in the present application by modifying Domazakis and adopting the process as disclosed by Hendricks, without exercising additional experimentation.

Domazakis describes a process for the preparation of ***emulsion-type meat based products*** made of ***thin-chopped meat***, that includes the step of adding olive oil after the thin-chopped meat has been mixed with water, *salt, polyphosphoric salts, preservatives, vegetable proteins, milk proteins and starch* using a ***machine of mixture*** (e.g. a meat grinder or cutter) (see Domazakis paragraphs [0001]-[0007], [0011]-[0012], [0031], [0038]).

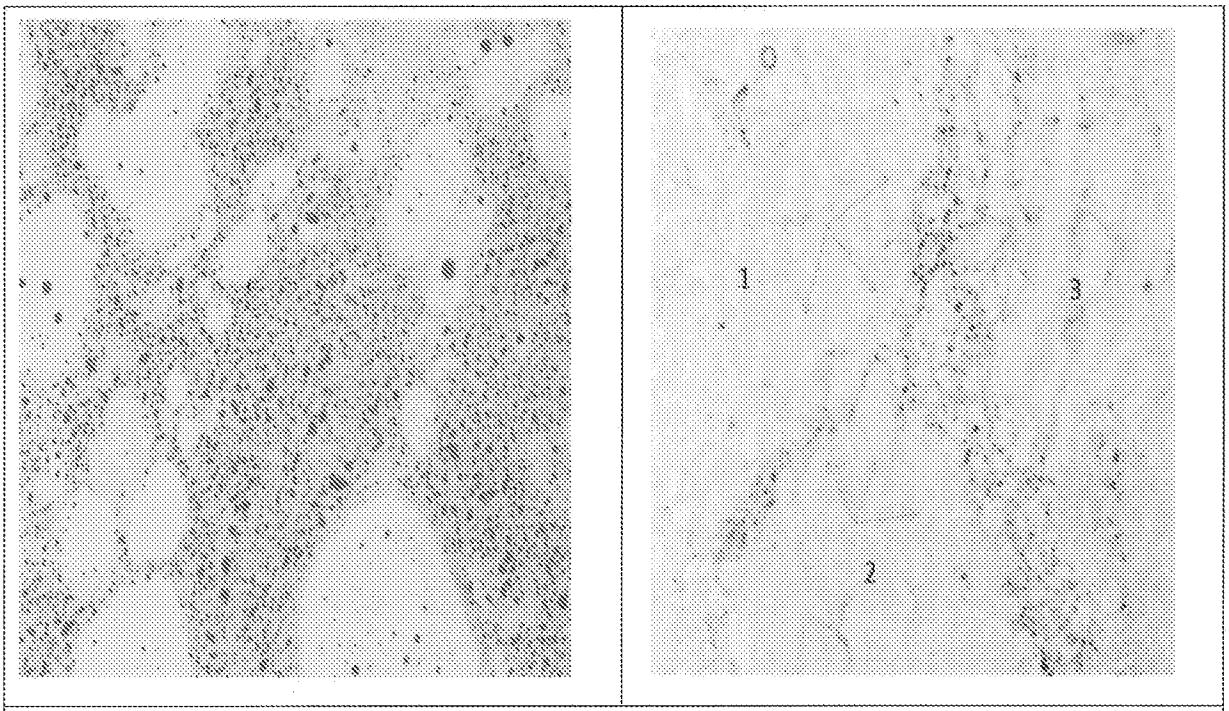

Image 1: **On the left:** Microscopic view (x200) of a section of a meat emulsion-based product, containing olive oil (hot dog), stained with Nile Red (lipid staining). The lipid droplets are stained in red. **On the right:** Microscopic view (x20). Localization of dispersed oil droplets (stained in red), in a section of entire muscular tissue product, made according to the invention. Numbers indicate three separate pieces of meat and the different arrows, the indicative contact areas between them.

Comminution in combination with salt addition significantly alters the structure of a meat system. As seen from the above image (image 1-left), the oil (and fat) globules are dispersed throughout the mass of a complex meat system, containing soluble proteins, but also insoluble components, such as fragments of muscle fibers and connective tissue. To the contrary, the olive oil droplets, within an olive oil containing- product of entire muscular tissue, made by the present invention, are specifically localized at the surface of the meat pieces and thus, in case of joining together individual pieces of meat (in a mould), the oil droplets are mainly seen at the contact areas of the different meat pieces (image 1-right) (see below for further discussion with regards to this matter).

Domazakis discloses a process for the preparation of emulsion-type meat-based products by:

(a) mixing (i.e. not simply contacting) in a mixing machine, thin-chopped lean meat at temperature of 0°C with water at a temperature of -2°C, salt, poly-phosphoric salts preservatives, vegetable proteins, milk proteins and starch (i.e. no use of a brine),

(b) inserting olive oil and continuing mixing in the mixing machine with simultaneous vacuum until the resulting mixture reaches 4°C,

(c) encasing the meat mixture with simultaneous application of vacuum and pasteurising the encased meat mixture, and

(d) freezing the product in freezing chambers up to 2°C.

The method of the present application differs from Domazakis in at least the following aspects. First, Domazakis uses finely-chopped meat for the production of emulsion-type products (e.g. sausages, such as hot dogs). Second, Domazakis uses a technology for emulsion-type meat products. There is no teaching with regards to the technology of cured "entire muscular tissue"- based products as claimed in claim 3 of the present application. Finally, Domazakis faces the challenge of emulsion stability in emulsion-type products containing oil (image 1). To stably incorporate the oil therein, Domazakis adopts the following problem-to-solution approach:

a. The finely-chopped meat is mixed with a number of additional non-meat ingredients, such as salt, poly-phosphoric salts, milk proteins, vegetable proteins and starch.

b. Olive oil is inserted after the admixture of the aforementioned ingredients (i.e. salt, poly-phosphoric salts, milk proteins, vegetable proteins and starch) and the mixing stops when the temperature is 4°C.

However, Domazakis fails to disclose at least the following features of claim 3 of the present application (also referred to as the '659 App.):

1. *producing* meat products from *entire muscular tissue,*
2. *injecting* entire muscular tissue *with brine,*
3. *tumbling* of the brine-injected entire muscular tissue,
4. *adding olive oil* to the *brine-injected and fully tumbled entire muscular tissue*, and
5. *tumbling after the addition of olive oil (a second independent step).*

On the other hand, Hendricks relates to methods, compositions and apparatus for treating and upgrading the tenderness and sensory qualities of ***fresh red meats***. Hendricks "provides a mechanism whereby low grades of meat maybe be made tender, flavourful and juicy [..]. This is accomplished by injecting the meat with ***appropriate injectates***. Such injectates may include unsaturated vegetable fats such as corn oil, water, and even beef tallow or other saturated fats. It is presently preferred to include a binder in the injectate..[..]". (see Abstract). Hendricks differs from the present application in at least the aspects outlined below.

First, Hendricks achieves an upgraded tenderness and sensory qualities of ***fresh red meats***, thus improving their market value. The '659 App. relates to entire-muscular tissue based ***processed and Ready-to-Eat products***, such as ham and turkey fillet (see the '659 App., paragraph [0007]), wherein oil is being stably incorporated. The Applicant, as well as Dr. Stephanopoulos (as evidenced by his Declaration), is of the opinion that a fresh meat piece, e.g. a steak, rib eye and round, as disclosed in Hendricks (e.g. see tables 1- 4) should not be regarded as being comparable (or similar) to a processed, ready-to-eat meat product. It is clear that injecting fresh meat with oil and the method in which an entire muscular tissue-based product

stably incorporates olive oil are two different processes and are therefore not able to be compared. (see the Declaration Sections 6 and 7).

Second, according to the basic technology of cured meat products, based on entire-muscular tissue, the meat pieces (previously injected with brine, comprising salt and curing agent) are subjected to mechanical working (tumbling). Mechanical working loosens the structure of the musculature, breaks up cells, and makes brine absorption easier. This in effect increases the mobilization of the extracted, soluble meat proteins. The solubilised meat proteins migrate to the surface, where they form an adhesive substance (paragraph [0008]).

"Processing" in the entire muscular tissue-based products of the present application, further includes *cooking*. Heat-induced gelation is a complex physicochemical process involving structural and functional changes of the proteins. It includes three stages, i.e. dissociation, thermal denaturation and aggregation. Partial unfolding of the protein structure is accelerated by an increase in temperature, which results in the aggregation of the unfolded regions between protein molecules to form a three-dimensional network. The structural and conformational changes that occur as a result of thermal denaturation enable the soluble meat proteins at the surface of the meat pieces (with myosin being the main representative of salt-soluble meat proteins) to gel. Heat-induced gelation of the adhesive substance at the surface of the meat pieces, helps sticking together pieces of tissue items, in order for the resulting product to attain its desirable morphology. Following a heat treatment step (i.e. pasteurization), the resulting product is usually stored in refrigeration conditions until the end of its shelf life.

As is shown by the above, the process associated with the technology of cured entire-muscle based meat products as claimed in claim 3 of the present application, has nothing to do with the preparation of fresh meat cuts found in the counter of a butcher or of a supermarket.

Therefore, there is a substantial difference between the specific ***Ready-to-Eat product*** (product of the '659 App.) and the ***Ready-to-Cook*** product (product of Hendricks).

Third, Hendricks makes use of an "***Injection apparatus***" (Column 6, line 38), which aims to **inject** certain compositions (i.e. injectates) into pieces of fresh meat (injection as a process is characterised by a number of parameters, including an injection depth). In this regard, the '659 App. does not provide any teaching whatsoever with regards to an injection mechanism delivering a fatty substance at an injection depth, into the mass of a muscular tissue. *The brine injection, as also discussed in our previous communication, has been employed for many years in the meat industry.*

Fourth, the problem faced by Hendricks, as well as the approach-to-solution employed is irrelevant to the present case. As mentioned above, Hendricks aims at upgrading the tenderness and sensory qualities of ***fresh red meats***, with the objective to improve their market value. Hendricks further points out the difficulty in retaining the injectate into the meat piece which, in the absence of a binder, has a tendency to cook out (Hendricks uses added ingredients, such methyl cellulose, a common water retention agent, usually applied as a thickener). Quite the contrary, the present application relates to a method of processed entire muscle-based meat products, wherein oil is stably incorporated, without the need of additives. (See also the Declaration at Section 7).

In the present case, a number of critical features, as underlined in the present invention, allowed for the stable incorporation of oil droplets, within the proteinaceous substance at the surface of the meat pieces. Using the method of the present application, the amount of extracted, salt-soluble meat proteins, (which migrated at the surface of the muscular tissue) successfully functioned as emulsifying agents, that stabilised the dispersed oil globules. Therefore, the oil

droplets are stably incorporated in the resulting cooked product, within the proteinaceous gel at the surface of the pieces of muscular tissue. Therefore, if individual meat pieces, processed according to the invention, are joined together in a mould, this proteinaceous oil-containing gel is seen at the contact area regions of the different meat pieces (image 2).

In summary, the localisation of oil incorporation in the obtained product, characterises the novelty of the '659 App. resulting product.

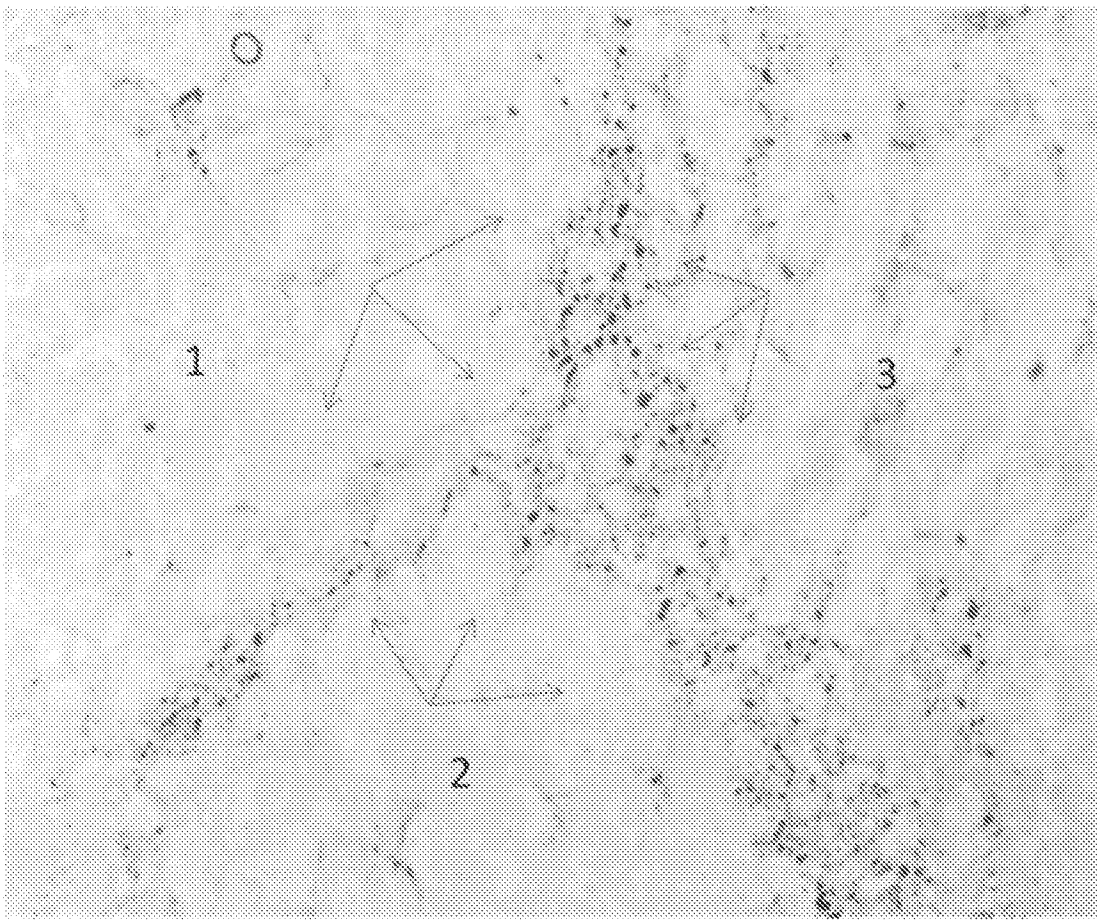

Image 2: (Microscopic view, x20). Localization of dispersed oil droplets (stained in red), in a section of entire muscular tissue cooked product, made according to the invention. Numbers

indicate three separate pieces of meat and the different arrows, the contact areas between them.

This characteristic of '659 App., is neither taught, nor indicated in any of the cited references, either examined individually, nor in combination of such references. With particular reference to Hendricks, the resulting product therefrom is characterised by the deposition/delivery of an injectate (comprising water, oil and a binder) composition that penetrates the mass of fresh meat piece and has nothing to do with the product and method of making such product as claimed in claim 3 of the present invention. (Compare with claim 16 – claiming "injection the meat by causing the injectate to flow from the nozzle at a sufficient pressure such that the injectate composition penetrates the meat and at least a portion of the injectate composition penetrates the existing connective tissue within the meat, wherein the injectate composition being injected into the meat so as to cut at least a portion of the connective tissue within the meat in order to mechanically tenderize the meat").

One of the largest challenges faced by the Applicant in his attempt to develop the said olive oil-containing meat products was the phenomenon of oil exudation and the hindered protein extraction (paragraph [0009]). This was a long and unresolved problem felt in the industry. (See the Declaration). The approach-to-solution, as claimed in the present application, comprises the steps of:

i. *injecting* entire muscular tissue *with brine,*

ii. *tumbling* of the brine-injected entire muscular tissue,

iii. *adding olive oil* to the *brine-injected and fully tumbled entire muscular tissue*, and

iv. *tumbling after the addition of olive oil (a second independent step).*

v. *maintaining a low temperature not exceeding 4°C prior to heat treatment.*

Hendricks is silent with regards to the technical features, underlined in the claimed method of the present patent. Therefore, Hendricks alone or in combination with the other cited references, does not teach each and every limitation of the method claimed in the present application.

The Examiner further asserts that Brandt discloses addition of various ingredients to the meat by either mixing, injecting, tumbling or massaging and that one of ordinary skill in the art would have been motivated to modify Domazakis in view of Brandt and to employ tumbling or injecting instead of mixing as an alternative technique for addition of various components to the meat. The Applicant kindly notes that "mixing, tumbling and massaging of meat" are not presented in Brandt as alternative methods to add various ingredients to the meat, but are rather used to "facilitate tenderization through disintegration of the muscle fiber sheath and stretching of the myofibrils." (see Brandt, page 2 of 7). Even if that was the case, Brandt clearly refers to a "marination system" or "marinating solution" that can be as simple as salt, phosphates and water, or more complex with flavours, seasonings, starches, vegetable or dairy proteins, acids, antimicrobials and antioxidants. The marinating solution/system neither in its simple, nor in its complex formulation, refers to a fatty substance, let alone olive oil in the exemplary amounts disclosed in the present application. Brandt points out that one of the keys to creating a functional marination system is to include ingredients that promote the capability of the muscle to bind water, such as salt and phosphates and those that actually bind water such as soluble proteins and starches. Therefore, by reading Brandt, the person of ordinary skills, is directed away from the use of a fatty substance, such as olive oil in the marinating solution. Further evidence is presented in the Declaration at Section 8. Moreover, Brandt refers to marinated fresh meat pieces, rather to cooked, ready-to-eat products.

The role of a marination system, as correctly addressed by Brandt, is to promote the capability of the muscle to bind water. In order to retain as much as possible of the added water (i.e. to increase product yield, tenderness and juiciness), proper compounds must be blended in the solution of the injectable brine. Sodium chloride, sodium phosphates (typically pyrophosphate), polysaccharide gums, soy or whey proteins, modified starches are common ingredients. The presence of these highly charged or hydrophilic, individual or mixed, compounds enables the injected meat to effectively retain water, thus increasing its yield and palatability. Notably, phosphates can very effectively increase charge repulsions between myofilaments and facilitate the removal of transverse myofibrillar proteins, which act as structural constraints to myosin extraction. The expansion of the myofilamental lattices allows water-binding and physical entrapment in the brine-treated meat. On the other hand, olive oil is a non-polar substance. It is not thus expected to raise the beneficial effect of increasing the water-binding capacity. Most importantly, it is common fact, that olive oil, being non-polar, will not dissolve in the water, as the water molecules will hydrogen bond to each other and will not allow the oil molecules between them.

According to the Applicant' s experimental work, the addition of oil, if it is carried out by the wrong manner and/or at the wrong timing, it is found to result in a number of undesirable phenomena. Inventive work was thus needed to develop the appropriate method, for the attainment of the desirable technical effect. One of the critical process features with a significant technical effect was the precise timing for olive oil addition, i.e. after the brine-injected meat has been fully tumbled (see Claim 3 (b), as originally filed: at the end of the tumbling, the olive oil is added). At that timing, the available amount of extracted meat proteins has been maximized due to the mechanical working of the meat in the tumbler. The solubilised meat proteins migrate to

the surface of the meat pieces and form an adhesive film that, in the present application, not only provides a sticky substance for binding the pieces of meat, in order to attain its desirable morphology, but also offers the appropriate matrix for the emulsification/entrapment/encapsulation of the oil droplets. The addition of olive oil at a wrong timing was found to result in the formation of an insulating layer that hinders the extraction or/and migration of the solubilised meat proteins to the surface of the meat pieces (see the '659 App. paragraph [0008]: "The admixture of fat hinders considerably the injection of various salts (e.g. nitrites) and the extraction of proteins ..[..].").

In summary, the critical technical features underlined in the claimed method, which are linked to one novel aspect of the '659 App., are absent in the cited prior art cited (i.e. Hendricks, Brandt and Domazakis). Even if a skilled person would have attempted to combine the teachings of Hendricks and Domazakis, he would still not arrive at the subject matter of '659 App. In particular, either taken individually or in combination, Domazakis and Hendricks fail to disclose certain critical technical steps, which led to the contribution to the art and the surprising effect of the claimed method, in particular (1) *adding olive oil* to the *tumbled and brine-injected entire muscular tissue*, and (2) *tumbling after the addition of olive oil (a second independent step)*. (See the Declaration Section 8). By combining the cited art, the skilled person would have rather considered to use an injectate, the way disclosed in Hendricks, having as a "binder" (see Hendricks, e.g. column 6, lines 23-25) a composition comprising a combination of ingredients as disclosed in Domazakis (i.e. preservatives, polyphosphates, vegetable proteins, milk proteins and starch). There is no such disclosure in the '659 App. Following Brandt, in combination of Domazakis and Hendricks would still not go the person of ordinary skills any further, as it would only teach him how to optimise the marinating solution and employ different methods to

facilitate tenderization. Most importantly, for the reason that Brandt clearly teaches that "All of the ingredients should be dispersed in ambient temperature water for proper dissolution" (see page 2, third paragraph), the person of ordinary skills would rather not consider the said reference any further.

In summary, the method and product derived therefrom taught by the claimed method of the present invention is also novel and inventive, in view of the cited prior art because (1) Domazakis relates to an emulsion-type product, containing olive oil; (2) Hendricks discloses fresh meat pieces having been injected (i.e. delivery of a liquid into the muscular tissue at an injection depth) with an injectate, that preferably also includes an added ingredient, such as methyl cellulose, a conventional water retention agent, often used as a thickener); and (3) Brandt describes marinating solutions for the preparation of fresh marinated meat pieces. The marination solution contains ingredients that promote water binding capacity.

Applicant therefore respectfully submits that neither Domazakis nor Hendricks nor Brandt nor any legitimate combination thereof teaches or suggest all of the limitations of claim 3.

III. Conclusion

Applicant respectfully submits the claims and the application are in condition for allowance and such is courteously solicited. If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard. Should any fees be necessitated by this response, the Commissioner is hereby authorized to deduct such fees from Deposit Account No. 11-0160.

Respectfully submitted,

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